JUN 13 2014

510(k) Summary of Safety and Effectiveness

Submitter Information	
Name	United Orthopedic Corporation
Address	No 57, Park Ave 2, Science Park, Hsinchu 300, Taiwan
Phone Number	+886-3-5773351 ext. 2212
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Name of Contact Person	Fang-Yuan Ho Regulation and Document Management
Date prepared	January 10, 2014
Name of Device	
Trade Name	U2 Femoral Component, CR, Porous Coated
Common Name	Femoral Component
Classification Name and Regulation	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis under 21CFR § 888. 3565
Device Class	Class II
Classification Panel	Orthopaedics
Product Code	MBH
Predicate Device	1. "United" U2 Total Knee System (K051640) 2. "Smith & Nephew" Genesis II Total Knee System (K030612)

Device Description:

U2 Porous Coated Femoral Component—CR Type is manufactured from Co-Cr-Mo alloy confirming to ASTM F75. The inner surface is porous coated with Co-Cr-Mo beads (ASTM F75) to provide a porous surface for enhanced fixation. It is available in seven proportional sizes (#1~ #7, AP/ML ranging from 52mm/ 56mm to 76mm/ 80mm) and is provided in left and right configurations. The femoral component is the same as that of

cleared U2 Total Knee System (K051640), except adding size #7.

Intended Use:

The U2 Total Knee system is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee cannot be satisfactorily balanced and stabilized at the time of surgery.

For cemented femoral components, patellar components, tibial baseplate components and tibial inserts components: This device is a single use implant and intended for cemented use only.

For porous coated femoral component: This device is a single use implant and intended for cementless use only.

Comparison to Predicate Device:

U2 Porous Coated Femoral Component—CR Type has the same materials, design, manufacturing and sterilization method as the femoral component of "United" U2 Total Knee System (K051640), except adding size #7. Besides, the basic design, size distribution, intended use of the subjected device and the method of fixation are similar with the femoral component of "Smith & Nephew" Genesis II Total Knee System (K030612).

Performance Data:

- **Non-clinical Performance**

  This 510(k) submission was prepared in accordance with the Agency's, " *Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and*

Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA". Tests as follows were conducted to evaluate the safety and effectiveness of the subjected device, and the test results demonstrated that this device is safe and effective.

a. Range of Motion
b. Contact Area and Contact Pressure on Femorotibial Joint
c. Contact Area and Contact Pressure on Femoropatellar Joint
d. Subluxation of Femoroltibial Joint
e. Fatigue Compression Test of Femoral Component

- **Clinical Performance Data/Information**

None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 13, 2014

United Orthopedic Corporation
Fang-Yuan Ho
Regulatory Affairs Manager
No 57, Park Ave 2, Science Park
Hsinchu 300 Taiwan

Re: K140075
Trade/Device Name: U2 Femoral Component, CR, Porous Coated
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: March 24, 2014
Received: March 25, 2014

Dear Fang-Yuan Ho,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K140075

Device Name: U2 Femoral Component, CR, Porous Coated

Indications for Use:

The U2 Total Knee system is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee cannot be satisfactorily balanced and stabilized at the time of surgery.

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Prescription Use x AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices